Neutral Citation Number: [2020] EWHC 495 (Comm)

Case No: CL-2019-000064

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
COMMERCIAL COURT (QBD)

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Thursday, 13th February 2020

Before:

THE HON. MR. JUSTICE BRYAN

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Between:

CARDIORENTIS AG	**Claimant**
- and -	
(1) IQVIA LIMITED	
(2) IQVIA RDS, INC.	**Defendants**

- -

MR. PAUL STANLEY QC and MR. NOEL DILWORTH (instructed by **Hogan Lovells International LLP**) for the **Claimant**

MR. LAURENCE EMMETT and MR. BENJAMIN LEWY (instructed by **Cooley (UK) LLP**) for the **Defendants**

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APPROVED JUDGMENT

MR. JUSTICE BRYAN:

A. Introduction

A1 The applications

1. The parties appear before me today on the case management conference in two consolidated proceedings. In its first claim, Cardiorentis AG ("Cardiorentis") seeks damages for alleged breaches of duty committed in relation to a Phase III clinical trial of a pharmaceutical product ("Ularitide") which was developed with the intention of treating acute decompensated heart failure ("the Clinical Trial").

2. As to the second claim, IQVIA UK ltd, (i.e. the first defendant, referred to as "IQVIA UK"), seeks payments totalling about €16.5 million inclusive of interest in respect of unpaid invoices for work carried out as part of the Clinical Trial. The second defendant, IQVIA RDS, Inc (individually referred to as "IQVIA US", and collectively with the first defendant, "IQVIA"), is also part of the IQVIA group.

3. There are a number of applications before me on the case management conference. This judgment concerns the first application that is before me, namely Cardiorentis' application to amend its Particulars of Claim ("the Amendment Application").

A2 The Background Facts

The Contract

4. The IQVIA group specialises in coordinating pharmaceutical research: it is a contract research organisation or CRO. Cardiorentis AG is a company with rights in relation to Ularitide, and was conducting trials into its safety and efficacy by undertaking the Clinical Trial between 2011 and 2016 in 156 centres in 23 countries. A Phase III trial involves treating patients with either the investigative drug or placebo in a doubleblind randomised study. "Doubleblind" means that none of the patients, the investigators, the CRO or the sponsor of the trial knew which participants were getting the trial drug and which were getting the placebo.

5. The principal agreement which governed the conduct of the trial was a General Services Agreement ("the GS Agreement) dated 30th August 2012 between IQVIA UK and Cardiorentis. The GS Agreement was a kind of "master contract" supplemented from time to time by "Change Orders", i.e. specifications of particular tasks to be carried out by IQVIA and the associated commercial terms.

6. IQVIA US (and, Cardiorentis alleges IQVIA UK) also entered into a Clinical Quality Agreement ("the CQ") with Cardiorentis in April 2013. This agreement was, it is said, supplemental to the GS Agreement. It did not contain a choice of law clause. Cardiorentis alleges, but the defendants deny, that it was governed by North Carolina law.

7. Between August 2012 and May 2014, patients were identified, randomised (i.e., assigned to either the Ularitide group or the placebo group), and treated and then monitored until January 2016.

8. During the Clinical Trial, IQVIA made reports to Cardiorentis about the progress of the Clinical Trial, including the incidence of protocol deviations, of which eligibility deviations are a subset. The means by which this information was provided included, amongst other documents, what had been referred to as PD Logs, which were discussed at regular meetings.

9. Between around mid-February and mid-March 2016, the parties conducted the Blind Data Review process

   (1) This is the process of determining which patients' data should be included in the analysis. It is conducted by both parties. The process is conducted "blind" so those responsible for it are not influenced by knowing how their decisions might affect the results of the trial. Once the process is complete, the database is locked and the data is "unblinded". The dataset cannot be further amended;

   (2) During the Blind Data Review process, IQVIA provided Cardiorentis with further information about eligibility deviations. This included providing documents which have been called in these proceedings "the PD Listings" and "the PD Spreadsheets" (of which multiple versions were issued);

   (3) The last PD log issued before the database lock, which I understand was dated 24th February 2016, identified the number of PDs concerning entry and eligibility criteria at around 175. Cardiorentis' case is that it then believed, as a result of this information, that the number of such PDs was around that figure;

   (4) Cardiorentis decided to include in the statistical analysis all the patients who were subject to eligibility deviations of which it was aware;

   (5) On 11th March 2016, a database lock was effected;

   (6) On 16th March 2016, IQVIA sent Cardiorentis a new version of the PD Spreadsheet ("Version 1"), followed by several others, ("Versions 2 and 3"). Cardiorentis contends that the three "final" versions contain references to approximately 190 more patients than that which Cardiorentis claims had previously been believed by it to have been ineligible.

10. The data for the Clinical Trial was duly unblinded. IQVIA contends that on 22nd March 2016, Cardiorentis signed off on the PD Spreadsheet in more or less the same form as it had been sent by IQVIA on 16th March. The results of the Clinical Trial were the subject of a publication in the *New England Journal of Medicine* on 12th April 2017. The authors included Dr. Holzmeister (Cardiorentis' CEO).

11. It is common ground that the results of the Clinical Trial mean that the drug is unlikely to win regulatory approval for treatment of acute decompensated heart failure on the back of that trial. I say that because Cardiorentis, in this action, says that the reason for that is because that trial was polluted by there being too many ineligible patients within that trial. More than that, although some positive effect appears statistically to have occurred as a result of the application of the drug to those who should have been within the Clinical Trial, the same was not true for those who should not have been in the Clinical Trial.

Heads of claim

12. Cardiorentis claims damages for breach of the GS Agreement and damages for breach of the CQ Agreement. Those are claims in contract. It contends that the conduct of the Clinical Trial was flawed, in particular in two ways:

> (1) The number of patients who were included in the Clinical Trial without meeting the criteria was close to or exactly 365 out of 2,157, and so was so high that no regulator would accept the drug, because the results do not demonstrate efficacy to a sufficient level of statistical significance in relation to an appropriate group;
>
> (2) IQVIA did not properly tell it about the eligibility deviations when they should have done so. It is said that, therefore, the knowledge that Cardiorentis had was different to the knowledge which it would have had, if IQVIA had complied with their obligations.

13. I will have to return to the pleaded issues in relation to that and what Cardiorentis says are the consequences of that. The reason for that is because one of the issues raised Mr. Laurence Emmett, who appears on behalf of the defendants, is, it is said, that the pleading does not sufficiently plead what he characterises as "reliance".

14. Cardiorentis claims that the Clinical Trial cost approximately €69.5 million in payments to IQVIA UK, and approximately €28 million in other costs. Cardiorentis claims that this loss was incurred consequent upon the trial: it claims this loss as damages which it says flows from the breaches of contract on the part of the Defendants. For their part, IQVIA claims €16.5 million for unpaid invoices in respect of work carried out on the Clinical Trial. For its part, Cardiorentis says that it is not liable to pay that figure because it is entitled to set off its claim against that.

15. Further, Cardiorentis also contends that the CQ Agreement is governed by the law of North Carolina (as I foreshadowed) and so is subject to the Unfair and Deceptive Trade Practices Act ("the UDTPA"). Cardiorentis seeks to claim civil liability under that cause of action, which it is also said carries triple damages under North Carolina law.

Procedural History

16. There was pre-action correspondence in England between the parties in early 2017.

17. On 23rd March 2018, Cardiorentis issued proceedings against IQVIA in Durham County, North Carolina. These proceedings have been stayed until further order by a judgment of the North Carolina Business Court, dated 31st December 2018. In that judgment, it was stated that Cardiorentis did not dispute that the CQ Agreement was governed by English law. Cardiorentis has since appealed that decision and a hearing (I am told) before the North Carolina Supreme Court took place on 6th January 2020 with a decision expected by July 2020.

18. On 31st December 2018 IQVIA UK issued proceedings against Cardiorentis. On 1st February 2019, Cardiorentis issued its claim in damages in England against both of the IQVIA defendants. In the original Particulars of Claim, dated 4th July 2019, Cardiorentis only mentioned and relied upon IQVIA's issues of the PD Logs. It did not

mention the PD Lists or Spreadsheets. By an order of the court dated 5th August 2019, the two proceedings were consolidated.

19. IQVIA served their defence on 17th September 2019. In correspondence dated 26th September 2019, IQVIA expressed concerns relating to the factual case advanced in the original Particulars of Claim. Specifically, IQVIA allege that Cardiorentis' pleading contained the false allegation that Cardiorentis was only made aware of the eligibility protocols via the PD Logs, and that Cardiorentis had not properly dealt with other documents provided by IQVIA, namely the PD spreadsheets and the PD Listings. On 29th November 2019, Cardiorentis served a draft Amended Particulars of Claim (henceforth, "the draft APOC") and a Reply on IQVIA. I should say that the defendant consents to all parts of that draft, apart from Paragraphs 26A and 29. In the draft APOC, Cardiorentis set out various PD Listings and versions of the PD spreadsheet provided by IQVIA. In particular, Paragraph 26A and the other disputed parts of that draft, involved amongst other things, Cardiorentis contending that:

> (1)The PD Listings were not exclusively concerned with violations of exclusion or inclusion criteria, and that the PD Spreadsheet related to all protocol deviations;
>
> (2) the overall effect of the PD Listings, Spreadsheets and Logs was to continue to give the impression, it is said, to Cardiorentis, that figures for ineligible patients given in the PD Logs were materially correct. It is contended that this is because IQVIA did not present the data in a way that made the position clearly apparent and that the 24th February PD Log summary section was inaccurate.

20. IQVIA issued their Part 18 Request ("the RFIs") on 31st January 2020, seeking a response by 7th February 2020: that is seven days thereafter. Cardiorentis replied, stating that it would be unable to respond in full until 21 days.In those circumstances, one of the issues that arises for determination before me today is what of those requests for further information should be answered and within what timescale. I will need to deal with that in due course during the course of this hearing.

B The Amendment Application

B.1 The Legal Principles

21. A party may amend his statement of case, which has been served, either with the written consent of all other parties or with the permission of the court, (see CPR rule 17.1(2)). The principles on applications to amend are well-known and were ultimately common ground. I set them out myself in *Slater & Gordon v Watchstone* [2019] EWHC 2371, at [35]-[37], to which I have been referred, In summary:

> (1) When considering whether to exercise its discretion, the court should have regard to the overriding objective.. This involves the court striking a balance between injustice to the applicant in refusing the amendment and injustice to the opposing party and other litigants in general in permitting the amendment;
>
> (2) Permission to amend has in some reported cases been refused on the ground that the text of the amendment was insufficiently clear: *Swain Mason v Mills & Reeve LLP Practice Note* [2011] EWCA Civ 14 1 WLR 2735, at [107], cited in Volume 1 of the White Book at 17.3.5;

> (3) For amendments to be allowed, a party such as Cardiorentis must show it has a real, as opposed to a fanciful, prospect of success, which is more than merely arguable and carries some degree of conviction. A claimant does not have such a prospect *inter alia* where: (a) it is possible to say with confidence that the factual basis of the claim is fanciful because it is entirely without substance, and (b), the claimant does not have material to support at least a *prima facie* case that the allegations are correct: see, e.g: *Elite Property Holdings Limited and Another v Barclays Bank Plc* [2019] EWCA Civ 204 ("Elite Property"), at [4]. In this regard, and I quote from [42] in *Elite Property*:
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> "The court is entitled to reject a version of the facts which is implausible, self-contradictory or not supported by the contemporaneous documents"; (d) further, when one is considering whether there is a real prospect of success, one is doing a similar exercise as to what is done on a claim for summary judgment. Therefore, the principles which apply are the same. Authorities in the context of summary judgment have equal force and weight to an application to amend."

22. Thus, the commentary in the White Book (cited at [37] of *Slater & Gordon*), supported as it is by the various authorities referred to, is also apposite on an application for permission for amend:

> "The hearing of an application for summary judgment is not a summary trial. The court at the summary judgment application will consider the merits of the respondent's case only to the extent necessary to determine whether it has sufficient merit to proceed to trial. The proper disposal of an issue under Part 24 does not involve a court conducting a mini-trial (per Lord Woolf MR in *Swain v Hillman* [2001] 1 All ER 91). How the court decides whether a defence is real without conducting a mini-trial has led to a series of unsatisfactory cases now hopefully concluded by the clear statements of authority in *Three Rivers DC v Bank of England (No.3)* [2001] 2 All ER 513, HL (a summary judgment application; see especially, the speech of Lord Hope of Craighead at paras 94 and 95) and ED&F Man Liquid Products Ltd v Patel [2003] EWCA Civ 472 (a set aside application; see especially paras, 9, 10, 11, 52 and 53 in the judgment of Potter LJ). At a trial, the criterion to be applied by the court is probability: victory goes to the party whose case is the more probable (taking into account the burden of proof). This is not true of a summary judgment application. 'The criterion which the judge has to apply under CPR Part 24 is not one of probability; it is absence of reality.' (Lord Hobhouse of Woodborough in *Three Rivers DC v Bank of England* (No.3), supra."

B2 Application of the Principles to the Facts

23. Certain of the amendments are accepted. The disputed amendments, as I have foreshadowed, are Paragraphs 26A and 29. Cardiorentis contend that it wishes to amend those paragraphs in its pleading in order to address IQVIA's reliance on additional documents (the PD Spreadsheets and the PD Lists) and specify more clearly the documents on which Cardiorentis relies. IQVIA contends that permission to amend should not be granted for three reasons, which I will deal with in turn.

The First Contention

24. IQVIA contends that the case previously advanced by Cardiorentis, was "materially wrong", and that Cardiorentis has not explained why it did not previously advance the case that it now seeks to advance in the draft amended Particulars of Claim.

25. Whether or not Cardiorentis' previous case was "materially wrong" and the explanation for how that case came to be pleaded are not relevant matters to the question of whether an amendment should be allowed. At most, these matters go to the overall merits of the previous pleading. If it was or remains liable to be struck out, then the appropriate remedy is such an application. If it or the proposed amendments raised questions as to why the case was originally pleaded as it was or why it is now pleaded differently, then that is a matter in due course for cross-examination of witnesses appearing on behalf of Cardiorentis.

26. Further, I do not consider that IQVIA are entitled to an explanation as to why the original case was advanced in the way it was. They have an explanation as to the circumstances in which it has now been pleaded as it is - namely a review of the material that has been drawn to Cardiorentis' attention by IQVIA. I should say in that regard that these amendments do not amount, in fact, to any new cause of action and are, essentially, further particulars of what remains the existing plea. There are very few deletions to the pleading, apart from one incorrect reference to an e-mail.. In other words, the gravamen of the allegations made previously and made now are the same, supplemented by the additional material in the amendments.

The Second Contention

27. IQVIA says that the case which Cardiorentis wishes to run is inherently implausible.

28. On an application for permission to amend, the Court will not descend into a consideration of the merits going beyond that which is necessary to consider the application, applying the relevant legal principles that I have identified I do not consider that those principles to be apt in the present case, because the paragraphs that are objected to(26A and 29) in effect are further particulars of the existing plea.

29. However, to the extent that this is relevant, I am satisfied to the requisite level, for the purpose of this application, that the pleaded case (as advanced by the amendments), is not inherently implausible and it cannot be said that the claimant has no real prospect of success. In this regard:

> (1) Some of the PD Listings are pleaded to be inaccurate: namely, PD Listing 9 as provided on 9th February 2016 and 12th February 2016 and PD Listing 2. Cardiorentis are pleading that as at 3rd March, IQVIA had not provided any accurate PD listings which properly reflects Exclusion Criterion 3 or Exclusion Criteria 2 or 6. Therefore, the total number of patients who are ineligible by reason of those criteria were not appreciable from the PD Listings.
>
> (2) Further, Cardiorentis allege that it could not reasonably tell from the PD Spreadsheet sent before the database lock and the one sent on 16th March that the number of PDs to be excluded was higher than in the logs, because those spreadsheets included a column purporting to provide that information, but (it is

said) did so inaccurately. It pleads as follows: (a) none of the PD Spreadsheets were covered by an express statement to the number of PDs resulting in ineligibility under Exclusion 3 or Inclusion Categories 2 or 6; (b) there was additionally a column in the PD spreadsheet headed "Violation of Exclusion/Conclusion Criteria". It is said that if filtered by that column, the PD Spreadsheets identified 164 cases where the data confirmed a violation, or were marked "TBC", which it is said was materially inaccurate; (c) therefore, Cardiorentis contend that it was only possible to ascertain a reasonably accurate number of ineligible patients if the reader realised that the column dealing with that question was wrong and manually altered the spreadsheet to work out the correct number.

(3) If the aforementioned pleading reflects the contents of the PD Logs and Spreadsheets, it is reasonable to assume that a careful scientist might rely on the spreadsheet provided without performing his own checks.

30. I am satisfied that the pleas which are advanced in Paragraph 26A and 29 are both coherent and reasonably arguable.

The Third Contention

31. The reality is that by the time of the hearing before me today, the first two points relied upon on behalf of the defendants (i.e. requiring an explanation as to why the original pleading was as it was, and also to suggest that the amendment was inherently plausible) were not at the forefront of Mr. Emmett's submission, wisely in my view. Instead, Mr. Emmett concentrated upon the third of the objections to the amendment, which was, it is said, that Cardiorentis' case is defective in that it does not provide proper particulars of what he referred to as “reliance”.

32. If one looks at Paragraph 26A and Paragraph 29, and indeed later paragraphs including Paragraph 38 and 39, to which I was taken, it is clear that Paragraph 26A itself has nothing to do with the question of reliance. What it is doing is providing further particulars of alleged breach, of the applicable alleged contracts. It is, therefore, by its very nature, simply supplementing the existing pleaded claim that exists.

33. It is important to recognise that this is not, contrary to the impression given by the submissions on behalf of the defendants, a claim where reliance is an essential element of the cause of action, (e.g. a claim in deceit or a claim for various forms of misrepresentation). On the contrary, the current claim is essentially a claim for breach of contract based on express and alleged implied terms. It is right that there are references to Cardiorentis and the question of knowledge in Paragraph 26A ~~and in particular in Paragraph 26A(xi) and, also, in subparagraph (d),.~~ So, for example, in (ix), it is said that the total number of patients who were ineligible by reason of violation of Exclusion Criteria 2 or 6, or Exclusion Criteria 3, or all of them, was not apparent from the PD Listings 1, 2 and 9, and even in their final form IQVIA did not provide that figure. Nor did they alert Cardiorentis to the fact that, or the risk that, the number of ineligible patients was materially different from those identified in the PD Logs.

34. Equally, subparagraph (d) provided as follows:

> "The overall effect of all the information provided between 15th January 2016 and 16th March 2016 together in the light of

> the previously provided PD logs and in the absence of any clear indication to the contrary, was to continue to give the **claimant** the impression and/or not correct the impression that the figures for ineligible patients given in the PD logs was materially correct. The defendants did nothing to alert the **claimant** to the fact that the PD logs were not accurate and the PD listings would not have revealed any reason to doubt the accuracy of the PD logs, except by manually counting the number of patients listed on them; there was no reason to think that exercise was necessary. The defendants did not present the data in a way that made it clearly apparent and continued to provide data in the form of the updated PD log of 24th February 2016 and the PD spreadsheet column purporting to deal expressly with the question to the contrary effect."

35. It will be seen that Paragraph 26A, therefore, is both providing particulars of other documents (the Spreadsheets and the Listings) and also saying that the matters in those particulars impacted upon the knowledge that Cardiorentis had. It is correct that in those paragraphs the natural persons representing Cardiorentis are not specifically identified. Mr. Paul Stanley QC, who appears on behalf of Cardiorentis in this matter, acknowledges that it would be a proper subject matter of a request for further information to identify who it was being alleged had that knowledge. I agree, and as I will come on to, any permission I give in relation to this application will involve the provision of further information in relation to that knowledge. I should say, however, that I do not consider that the mere absence of identification of the individuals concerned renders the pleading defective.

36. As can be seen, Paragraph 26A is essentially concerned with knowledge. Paragraph 32 then deals with breach and at Paragraph 39, the damages claimed are set out.

> "39. As a result of the first and/or second defendant's breach of contract: (a) by the time of the BDRM, the claimant did not have a reliable understanding of the instance of the irregularities referred to above, including in particular the incidents of randomised or eligible subjects or the irregularities concerning the University of Kansas Medical Centre at Site 0401; (b) the claimant was thereby deprived of the opportunity to carry out a proper assessment of the impact of protocol deviations or to make decisions prior to unblinding the data following the database lock with respect to the analysis and reporting of the data and any further amendments to the arrangements for the AHF Clinical Trial."

37. In response to Cardiorentis' pleading, in the IQVIA's defence, at Paragraph 43(5) IQVIA pleaded as follows:

> "Cardiorentis does not allege that it would have made different decisions as to patient inclusion if it had believed at the time of database lock that will had been 368 eligibility deviations."

38. That plea was responded to by Cardiorentis in the reply, at Paragraph 30, and I quote:

> "As regards paragraph 43(5) the claimant's case as to its loss is set out in paragraph 39 of the particulars of claim. It is specifically averred that the options which would have been available to it, if it had been informed by the defendant (or one of them) in a timely or reasonable manner about the true instance of eligibility violations would have included any or a combination of the following:
>
> (a) The claimant could (and in circumstances where it was informed promptly about the true incidents of such violations at a particular site, is likely to) have approved or encouraged the intensification of training and monitoring of the investigators at the site in question;
>
> (b) In the event of persisting violations at a particular site, such as at the sites identified in paragraphs 21(a)-21(g) of the particulars of claim, the claimant would (and in circumstances where it was informed promptly about the true incidents of such violations at such a site is likely to) have approved or encouraged the closure of clinical trial activity at certain sites and discontinued conduct of the true/AHF Clinical Trial at the relevant sites;
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> (c) If aware of the true incidents of eligibility violations, the claimants would (and in the circumstances is like likely to) have considered incorporating a modified IDT analysis in order to address ineligible patients; and/or
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> (d) The claimant would (and in circumstances where it was informed promptly about the true incidents of such deviations at such a site is likely to) have approved the prolonging or amplifying the power of the true/AHF Clinical Trial and the number of patients randomised, so as to reduce the overall percentage of eligibility by violations."

39. It will be seen, as I have already foreshadowed, that Paragraph 26A in fact is concerned with knowledge and is not, in fact, concerned with reliance, certainly in the legal sense. I do not consider the fact that Paragraph 26A does not particularise matters of reliance to be an objection to the granting of permission in respect of Paragraph 26A. Indeed, it would be surprising if Paragraph 26A contained any particulars of reliance, because it is not a paragraph which purports to deal with reliance. It is a paragraph that deals with breach.

40. I understand Cardiorentis' case to be, firstly, that there are various express and implied contractual obligations. Those obligations were then allegedly breached, both in relation to monitoring and reporting, including in relation to deviation in relation to ineligible patients, and Paragraph 26A is identifying aspects of those breaches, and the circumstances in which Cardiorentis did not have knowledge which implicitly it says it should have had, and would have had, had IQVIA complied with their contractual obligations in that regard. There are other paragraphs in the pleading which I have

identified, including Paragraph 39, which look towards the consequences of that. I accept that in a wider and more general sense, reliance is relevant to Cardiorentis' case, in the sense of a decision to act based on knowledge (or lack thereof) and reliance may be relevant when one comes to questions of causation and the plea of contributory negligence. However none of those matters relate to Paragraph 26A. Nor, indeed, do they relate to the other paragraph in relation to which objection was taken, which is Paragraph 29.

41. Paragraph 29, in its amended form, provides as follows:

> "On 16th March 2016 when the defendant sent the claimants the three final versions of the PD spreadsheets, described at 26A and (b)(v)-(vi) above, those did include reference individually to 186 further patients in addition to those identified by the time of the database lock, randomised in violation of the eligibility criteria. Neither the PD spreadsheets, nor the relevant correspondence from the IQVIA when submitting these updated versions drew the claimant's attention to the true number of the ineligible patients included in the true/AHF Clinical Trial. Nor was this readily identified or apparent from the way in which the data was presented in each PD spreadsheet. On the contrary, as set out above, the PD spreadsheets included a column which purported to provide this information, but which did so inaccurately."

42. Again, I see nothing inappropriate or incoherent about paragraph 29. It is providing further particulars of the matters there set out, and also correcting errors in initial pleadings. The consequence of that, of course, in the normal way, is that IQVIA will get their costs of and occasioned by the amendments in responding to that corrected pleading. That pleading, again, is not concerned with reliance. I am satisfied, so far as it is the sort of paragraph that can carry with it particular prospects of success, that it is a proper plea and that there are reasonable prospects of success of the allegations there pleaded out. Those allegations are supported by the factual matters there stated, and are reasonably capable of being demonstrated at a trial. Therefore, again, I cannot see any valid objection to that.

43. Mr. Emmett's final fallback position is a wider objection, that taking the whole of the pleading, it is not clear to IQVIA whether or not it is being said that Cardiorentis, and particular individuals within Cardiorentis, relied upon information and would have acted in a particular way depending on what information they had. I do not accept that this is a fair reflection of the state of the pleadings. As I have highlighted, Cardiorentis identifies the permutations of what could have been open to it in so far as it can based on what is a hypothetical question, (given that this is not what was done by IQVIA) and sets out its positive case as to what would have happened.

44. Therefore, the objection based on a failure properly to particularise a case based on reliance is, I am satisfied, not a valid reason to object to the amendments which are sought to paragraphs 26A and 29, or, indeed, to the pleading as a whole. It did, however, become quite clear to me during the course of hearing the debate between Mr. Emmett

and Mr. Stanley that this "issue" as to "reliance" required clarification. Accordingly, I indicated to Mr. Stanley that I considered it would be appropriate that further information was provided in relation to who is alleged to have had the requisite knowledge, and how they would have been likely to act on the basis of knowledge, clarifying precisely what Cardiorentis' case is in relation to the consequences of the matters which it pleads. Mr. Stanley indicated on instructions that he was prepared to provide that information, and indeed would do so, and I consider that it is appropriate that he does so.

Conclusion

45. Accordingly, and for the reasons that I have given, I consider that it is appropriate that permission be granted for the amendments which are sought. That is subject only to the provision of further information in relation to who is being referred to in relation to the reference to Cardiorentis. I have a confirmation from Mr. Stanley that there are, indeed, individuals that fall within that rubric and, therefore, the concern of IQVIA (that in fact there was no one who so relied or at least no one who is going to say they so relied) is unfounded. Having been given that reassurance, I am satisfied that it is appropriate to grant the permission sought.

46. The question of what is appropriate further information is not a condition of the amendment application, and I will deal with that in the context of the request for further information together with the other matters that arise on the CMC.